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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,805	02/12/2004	Scott L. Diamond	53893-5043	5374

23973 7590 12/07/2007
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18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

MAIL DATE	DELIVERY MODE
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12/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/777,805	Applicant(s) DIAMOND ET AL.	
	Examiner Richard Schnizer, Ph. D.	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-18, 22-26, 30-52, 54 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-21, 27-29, 52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment was received and entered on 10/31/07.

Claims 1-18, 22-26, 30-52, 54, and 55 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/27/07.

Claims 19-21, 27-29, 52, and 53 are under consideration to the extent that they read on the elected invention of a cationic nonviral delivery vehicle, made by mixing together a steroid, or modification or derivative thereof, a conjugating agent, and a polyamine, wherein the conjugating agent conjugates the polyamine to the steroid or modification or derivative thereof, purifying the conjugate, and mixing it with a lipid.

All rejections and objections not reiterated are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 21, 27, 29, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20 and 21 are indefinite in their recitation of "a modification or derivative thereof". The specification provides no standard for determining the scope of the

genuses of modifications or derivatives, and one of skill in the art could not know the metes and bounds of the claims.

Claims 27, 29, and 53 are indefinite because they recite "the C-21 position of said drug" without antecedent basis. The scope of the term "drug" is broad, and is not limited to compounds that have at least 21 carbons. Because the term embraces drugs with less than 21 carbons, the claims recite "the C-21 position of said drug" without proper antecedent basis.

Response to Arguments

Applicant's arguments filed 10/31/07 have been fully considered but they are not persuasive. Applicant argues at page 14 of the response that the phrase of "a modification or derivative thereof" has been removed from the claims. This is persuasive regarding claims 27-29, 52, and 53. However, the phrase was not removed from claims 20 and 21, so they remain rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-21, 27-29, 52, and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

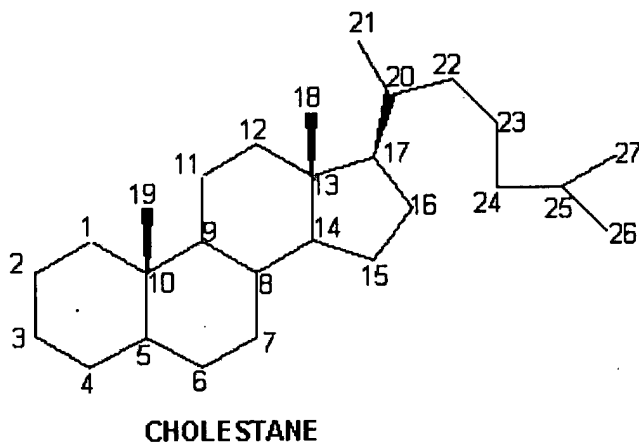
reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 is drawn to the genus of dexamethasone-spermine molecules with a spermine constituent attached through the C-21 position of the dexamethasone moiety. This genus fairly embraces a molecule in which spermine is attached directly to C-21 of dexamethasone. The specification as filed disclosed methods of conjugating spermine to dexamethasone through the use of conjugating reagents that leave a bridge between dexamethasone C-21 and spermine. See e.g. Fig. 1B in which 2-iminothiolane is used to conjugate spermine to dexamethasone, resulting in the addition of a butyl thioether linker between C-21 and spermine. The specification as filed did not disclose direct conjugation of any polyamine directly to C-21 of any steroid. Accordingly, one of skill in the art could not conclude that Applicant was in possession of a dexamethasone-spermine molecule with the spermine attached directly to C-21 of dexamethasone at the time the application was filed.

Claims 20, 21, 28, and 52, are drawn to the genus of molecules with a steroid conjugated to a polyamine via a conjugating agent, wherein the conjugating agent conjugates the polyamine through C-21 of the steroid. The specification as filed was generally directed to the modification of sterols comprising a C-21 hydroxyl group, or other C-21 reactive group (e.g. dexamethasone, 11-deoxycorticosterone-21-mesylate, corticosterone-21-mesylate, 11-dexoxycortisol-21-mesylate, cortisol-21-mesylate, 21-chloro-17-hydroxyprogesterone, dexamethosone-21-mesylate, and prednisone 21-mesylate, see page 4, lines 10-13, and page 15, line 20). However, the specification as

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filed did not disclose conjugation of a polyamine to C-21 of many other steroids, such as cholesterol, cholestane, and other steroids in which C21 is a methyl group constituting a branch of C-20, wherein C-20 is also bonded to a linear chain of carbons comprising e.g. C22-C26. See below.



Accordingly, claims 20, 21, 28, and 52 recite new matter because they embrace conjugates with a polyamine added to C-21 of cholesterol or cholestane, and other similar sterols with a C-21 that forms a branch from C-20 and is not a reactive group suitable for reaction with the disclosed conjugation agents.

Claims 27, 29, and 53 are drawn to the genus of compounds with a polyamine conjugated to any drug through the C-21 position of a drug. The specification does not disclose conjugation to the C-21 position of any non-steroid drug. Accordingly claims 27, 29, and 53, which embrace the conjugation of a polyamine to C-21 of any drug, also recite new matter.

Conclusion

No claim is allowed.

This application contains claims 1-18, 22-26, 30-52, 54, and 55 drawn to an invention nonelected with traverse in the reply filed on 2/27/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the

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hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Richard Schnizer, Ph.D.
Primary Examiner
Art Unit 1635